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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,332	05/01/2006	Eran Lavi	13425/1	9275
26646	7590	01/24/2008		
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			EXAMINER PATEL, TARLA R	
			ART UNIT 3772	PAPER NUMBER
			MAIL DATE 01/24/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,332

Applicant(s)

LAVI ET AL.

Examiner

Tarla R. Patel

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-16 and 18-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7, 15, 16 and 26-45 is/are rejected.
- 7) ☒ Claim(s) 6, 8-14 and 18-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

Therefore, "a deformable member attached at a posterior end of a pair of ribs on at least the lingual side thereof" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application

must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The amendment filed 11/8/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Amended specification discloses on page 3 line 10 paragraph starting with please add the following paragraphs for figures 9 and 10 as disclosed in amended specification, Fig. 9 is another perspective view of the protection of fig. 5, showing a magnified view of a chamber in which edible or beneficial material can be contained and fig. 10 is a schematic illustration of a control device contained within the chamber of fig. 9 are new matter to originally filed specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

3. Claim 1 is objected to because of the following informalities: the claim 1 recites the limitation "said member" must be "said deformable member" for clarity and consistency of claim language. Appropriate correction is required.
4. Claim 26 objected to because of the following informalities: The claim 26 depends from the claim 17, which has been cancelled, examiner interprets as claim 26 depends from claim 18. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3, 5-16 and 18-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recitation of "a deformable member attached at a posterior end of a pair of ribs on at least the lingual side" is not clear to the examiner.

Applicant's original presented specification fails to describe that what is deformable member? And deformable member is not shown in drawings.

7. Claims 1 and 40 recite the limitation "a pair of ribs" in claim is not clear, it must be "ribs". There is insufficient antecedent basis for this limitation in the claim.

8. Claims 1 and 40 recite the limitation "the lingual side" in claim is not clear, it must be "lingual side". There is insufficient antecedent basis for this limitation in the claim.

9. Claims 1 and 40 recite the limitation "the yield" in claim is not clear, it must be "a yield". There is insufficient antecedent basis for this limitation in the claim.

10. Claim 5 recites the limitation "the two substantially U-shaped ribs" in claim is not clear, it must be "two substantially U-shaped ribs". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-3, 5, 7, 15-16, 27-31, 33-37, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Meade (6,055,986).

Meade discloses a device for separating between the upper and lower jaws (column 5 lines 46-65, see fig 11) comprising at least two substantially U-shaped ribs (120, 130) and a deformable member (142 and 144) attached at a posterior end of the ribs(attached by means of block 158, as described in column 11 lines 60-62) on at least lingual side (as shown in figures 7-10) thereof such that deformable member gradually changes its shape when a pressure is applied on ribs by the jaws (column 9 line 56-column 10 line 6). Further, Meade discloses a yield strength of said ribs to be significantly greater than that of the deformable member (column 9 line 22-39 and column 9 line 56- column 10 line 6).

With respect to claim 2, the device is a protection device which prevents a self-inflicting or externally inflicted injury, since it cover the jaws it inherently prevents injury.

With respect to claim 3, the device is capable to suppressing upper airway resistance syndrome, since it permits the user to breathe through the opening (140, column 9 lines 52-55).

With respect to claim 5, the device comprises two U-shaped ribs (120,130) having a lingual (124,134) and buccal (126,136) side, each of ribs having a curvature corresponding to the curvature of a dental arch and subtending a majority of its length (see figs 7-11); two support units attached at each posterior end of a pair of ribs (120,130), (attached by means of block 158, as described in column 11 lines 60-62) on the lingual side, such that the two support units have bilateral symmetry about a plane coincidental with an anteriorly located central position of each of ribs and that each of ribs is separated one from the other (see figs 7-10), at a given point along a rib, by a separation substantially corresponding to an essentially maximum jaw angular opening when support units are not compressed; an upper and a lower tooth receiving means (128,138) for each support unit, each of tooth receiving means extending the entire length of a corresponding support units and adapted to retain posterior teeth, borders of each of tooth receiving means being defined by a wall of support unit (124,134 and 126,136) longitudinally protruding from a lingual side of a corresponding tooth receiving means and a portion of a rib longitudinally protruding from the buccal side (see figs 7-10).

With respect to claim 7, each support unit is provided with solid lingual walls (column 9 line 22-39).

With respect to claims 15 and 27, the central anteriorly disposed portion of each rib is an arcuate member for retaining incisor teeth on the buccal side, since the device has a wall with the central anteriorly disposed portion that is inherently arcuate shaped central anterior and it is capable of being place on a corresponding gum when the device is inserted within the oral cavity (please see figs 7-11).

With respect to claim 28, device is inherently prevent damage to the franulum of a corresponding lip, since device is arcuate in shape (Please see figs 7-11).

With respect to claim 30 and 31, device is inherently formed with a centrally and anteriorly airway (140, column 9 lines 52-55) for the release of vomit from the oral cavity between two opposing ribs and two opposing deformable members.

With respect to claim 33-34, the device is made of plastics, the material is same material for ribs and deformable member, plastics by nature have characteristic to harden after it is formed (column 9 line 22-39).

With respect to claims 35-37, the limitation "device is disposable and for one time use", "the device is reusable", and "device is packageable", all have been treated as an intended use recitations. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Since the limitation have not been positively claimed, it is inherent that the device of Meade can be disposable and for one time use, can be reusable, and it is capable of being packaged. With respect to claim 39, each support unit is configured in such a way and produced from a suitable material (plastic, column 9 line 22-39) so as to follow the movement of the jaws.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 16 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meade (6,055,986) in view of Kittelsen (5,460,527).

Meade substantially disclose the invention, see rejection to claims 1-5,7,15-16, 27-37, and 39 above; however Meade does not discloses that the device has a handle integrally formed with a rib, longitudinally inwards from the arcuate member and plurality of chambers.

However Kittelsen teaches a device having a handle (88) integrally formed with a rib, longitudinally inwards from the arcuate member (see fig 2 and 3) and plurality of chamber/pockets (84). At the time of the invention, it would have been an obvious to one having ordinary skill in the art to modify the device of Meade having a handle integrally formed with a rib, longitudinally inwards from the corresponding arcuate member and to have pockets as taught by Kittelsen, so the device can be used freely and person does not have to put their hand in the mouth to place the device in between the jaw and pockets to include the beneficiary agents applied to tooth.

15. Claims 40-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meade (6,055,986) in view of Tyler (6,244,269).

Meade substantially disclose the invention, see rejection to claims 1-5,7,15-16, 27-37, and 39, Meade further teaches a rib or reservoir; however Meade does not discloses that the device further comprise at least one reservoir suitable for housing a beneficial or edible material, the beneficial

and edible material is a scent or taste additive to the oral cavity, the beneficial or edible material is in the form selected from the group of liquid, aerosol, powder, gas and encapsulated form, each reservoir is a recess formed in the deformable member and a method for delivering material to a subject by providing a device with two U-shaped ribs, connected one end to one another and deformable member positioned between them, fitting each of at least one reservoir with a beneficial or edible material, inserting device into the oral cavity of subject such that deformable member separates and upper set of posterior teeth from lower set and allowing beneficial or edible material to be delivered to the subject upon application of pressure onto deformable member by the jaws.

However Tyler teaches a two piece pliable, edible, flavored mouthpiece (abstract), which can also be made using other materials such as flavored silicone, flavored plastics, (column 5 lines 25-29) and can also include flavored liquid centered (column 3 lines 45-49). At the time invention was made it would have been obvious to one having ordinary skill in the art to use the material of flavored plastic or flavored liquid centered as deformable material in the reservoir of Meade, as the material taught by Tyler to have better tasting device.

With respect to claims 40-44, a method of for delivering material to a subject the device of Meade and Tyler disclose the structural limitations of the invention (see above). Therefore it would have been obvious to one having ordinary skill in the art to perform the steps of inserting the device into the oral cavity of subject, such that the deformable member separates an upper set of posterior teeth from a corresponding lower set of posterior teeth and allowing beneficial and edible material to be delivered to subject. The edible or beneficial material can be delivered upon application of pressure by the jaws on said device, by the temperature within the oral cavity of the subject being greater than a predetermined value, by moisture level within the oral cavity of the subject being greater than a predetermined value, or after a predetermined time of having the device inserted into the oral cavity.

16. Claims 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meade (6,055,986) and Tyler (6,244,269) further in view of Schaefer et al (5,490,520).

Meade and Tyler substantially disclose the invention as claimed, see rejection to claims 40 above; however, Meade and Tyler do not discloses that the beneficial and edible material is delivered to a subject a by control

means, which can be one electronic component and circuitry, that the reservoir is suitable for housing the control means, and that the control means controls electric current and /or saliva secretion.

However Schaefer et al teaches a dental appliance for treating bruxism by means of a device including electronic circuitry (abstract). At the time invention was made it would have been obvious to one having ordinary skill in the art to include the control means of electronic circuitry as taught by Schaefer in the device of Meade and Tyler device to enhance or measuring the delivery of material to the subject.

17. Claims 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meade (6,055,986) in view of Pratt (5,323,787).

Meade substantially disclose the invention as claimed, see rejection to claims 1-5,7,15-16, 27-31,33-36, and 39 above; however Meade does not discloses that the device is packageable in a container which breaks upon removal of the device from said container and providing a retaining means for retaining the container in an accessible location.

However, Pratt teaches a custom fitted mouthpiece with storage container (Abstract). At the time invention was made it would have been obvious to

one having ordinary skill in the art to use the container keep the Meade's device as taught by Pratt to store the device.

Allowable Subject Matter

18. Claims 6, 8-13, 14 and 18-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

19. The following is a statement of reasons for the indication of allowable subject matter: The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found was the device having plurality of longitudinally disposed fins which are compressible upon application of jaw forces and which can return to their original dimensions following the relaxation of the jaw muscles, each fin comprises a first portion proximate to the first rib, a second portion proximate to a second rib, and a central arcuate portion connecting first portion and second portion, first and second portions being symmetrical about a plane which passes through a junction connecting first and second ribs and which separates a support unit into two separate sections, one reservoir suitable for housing a beneficial or edible material,

the beneficial and edible material is a scent or taste additive to the oral cavity, the beneficial or edible material is in the form selected from the group of liquid, aerosol, powder, gas and encapsulated form, each reservoir is a recess formed in the deformable member and a method for delivering material to a subject by providing a device with two U-shaped ribs, connected one end to one another and deformable member positioned between them, fitting each of at least one reservoir with a beneficial or edible material, inserting device into the oral cavity of subject such that deformable member separates and upper set of posterior teeth from lower set and allowing beneficial or edible material to be delivered to the subject upon application of pressure onto deformable member by the jaws and the beneficial and edible material is delivered to a subject a by control means, which can be one electronic component and circuitry, that the reservoir is suitable for housing the control means, and that the control means controls electric current and /or saliva secretion, further that the beneficial and edible material is a pharmaceutically active agents.

Response to Arguments

20. Applicant's arguments with respect to claims 1-3, 5-16 and 18-45 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tarla R. Patel whose telephone number is 571-272-3143. The examiner can normally be reached on M-T 6-3.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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